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Treatment Manual

Nonchemical Treatments

Irradiation

Contents

Introduction

General Information

This guide provides basic information concerning USDA policy, standards, and use of irradiation as a treatment process to eradicate invasive species of insects, diseases and plants, that may contaminate and be vectored by commodities and other transported items. These harmful invaders are holistically referred to as pests, or pests of plants. This guide also discusses procedures for the approval of facilities that use irradiation energy to mitigate pest to facilitate authorized movement of commodities in commerce. The use of irradiation or the approval of irradiation facilities for other purposes is outside of our scope.

This guide does not establish new regulatory requirements for conducting irradiation treatments, or moving articles treated by irradiation. Instead, it explains certain requirements already established in various APHIS regulations in the CFR; it describes actions that APHIS employees will take, at ports, irradiation facilities, and elsewhere, to enforce those regulations; and it describes a number of safeguards or best practices to comply with the regulatory requirements. A company may devise a facility design or procedure that complies with irradiation regulatory requirements but does not precisely match the options described in this guide. Such innovation may be acceptable. However, issuing a permit or certifying a facility might take somewhat longer in such cases. When the procedures do

not follow those described in this guide, APHIS employees will have to independently verify that they comply with regulatory requirements before issuing the permit or certifying the facility.

To be authorized to apply approved phytosanitary irradiation treatments, an irradiation facility shall first obtain a Certificate of Approval from USDA. (For details, see the section entitled "Certification of Irradiation Treatment Facilities," beginning on **page-6-8-1**.)

The regulatory framework that covers the use of irradiation against plant pests was originally published in the *Federal Register*, and later incorporated into the *Code of Federal Regulations*. Detailed citations are listed below:

- Irradiation phytosanitary treatment of imported fruits and vegetables. (Proposed rule; supplemental) 66 FR *in press* [Docket No. 98-030-3]. To be incorporated into the Code of Federal Regulations at 7CFR and 305 and 319.56.
- Fruit from Hawaii (Final rule). 63 FR 65645-65649, Nov. 30, 1998[Docket No. 97-005-2]. Incorporated into the Code of Federal Regulations at 7CFR 318.13-4f.
- Irradiation in the production, processing and handling of food. (Final rule). 62 FR 64107-64121, Dec. 3, 1997 [Docket No. 94F-0289]; *also*, 51 FR 13376-13399, Apr. 18, 1986 [Docket No. 81N-004]; *also*, 50 FR 15415-15417, Apr. 18, 1985 [Docket No. 84F-0287]. Incorporated into the Code of Federal Regulations at 21CFR 179.
- Irradiation in the production, processing, and handling of animal food and pet food (Final rules). 60 FR 50099, Sept. 28, 1995. *also* 58 FR 18148, Apr. 8, 1993. also 51 FR 8315, Mar. 11, 1896; *also*, 51 FR 5993, Feb. 19, 1986. Incorporated into the Code of Federal Regulations at 21CFR 579.
- Mediterranean fruit fly; additions to quarantined areas and treatments. (Interim rule). 62 FR 47553-47558, Sept. 10, 1997 [Docket No. 97-056-5]. Incorporated into the Code of Federal Regulations at 7CFR 301.78-10.
- Papaya, carambola, and litchi from Hawaii. (Final rule). 62 FR 36967-36976, July 10, 1997 [Docket No. 95-069-2]. Incorporated into the Code of Federal Regulations at 7CFR 318.13-4f.
- The application of irradiation to phytosanitary problems. (Notice of policy). 61 FR 24433-24439, May 15, 1996 [Docket No. 95-088-1].

- The use of irradiation as a quarantine treatment for fresh fruits of papaya from Hawaii. (Final rule). 54 FR 387-393, Jan. 6, 1989 [Docket No. 87-040]. Incorporated into the Code of Federal Regulations at 7CFR 318.13-4f.

Irradiation has been demonstrated to be effective in killing or devitalizing organisms that may contaminate and do harm to commodities or the ecosystems to which the commodities move. This energy source can thus be authorized for use in the treatment of regulated pests. Treatment may be mandatory, as a condition for the entry or movement of consignments, or it may be prescribed, based on the detection of regulated pests in commodities intended for transport. Alternatively, importers or exporters may voluntarily subject commodities to irradiation treatments in order to prolong their acceptability and desirability. Irradiation may thus be a treatment option, or it may be the only treatment which is approved for the pest and commodity in question.

As with all pest mitigation treatments, the objective is to minimize the risk of pest introduction through the use of exclusionary measures. The minimization of pest risk may be achieved through the use of treatments that have an acceptable level of efficacy. Treatments are approved that minimize the impact on the commodity and its ultimate use. The approval of irradiation, or any other technology as a pest mitigation treatment, does not favor that particular methodology. The purpose of these treatments is to minimize the pest risk and to maximize the safety associated with the movement and use of the commodity. Treatments and associated procedures are based upon science, and are no more restrictive than necessary to protect agricultural health.

For the purpose of this guide, the Animal and Plant Heath Inspection Service (APHIS) will usually function as the USDA representative in the use of irradiation for mitigating pests. Information concerning the use of irradiation and other pest mitigation treatments may be obtained from:

Oxford Plant Protection Laboratory
USDA APHIS PPQ
901 Hillsboro Street
Oxford, NC 27565

Approved Sources of Irradiation

The sources for energy commonly used in irradiation come from gamma-emitting isotopes (radio nuclides) of cobalt-60 or cesium-137; or from machine-generated sources which include (x-rays [bremsstrahlung] operated at or below an energy level of 5.0 MeV, or

electron beams operated at or below an energy level of 10 MeV). Any of these sources can be effectively used to devitalize pests that may be contaminants, thus eliminating the risk of relocating alien invasive species that pose a threat to agriculture or other ecosystems. The source and equipment used for pest mitigation treatments must be capable of safely and effectively irradiating the commodities to the specifications which are required for the targeted pests.

Location of the Irradiation Facility

Facilities approved by USDA for pest mitigation treatments may be located in the United States or outside the United States. Treatment facilities may be identified as being located within or outside an area where pests of concern are known to occur.

Actions Taken at the Port of Entry

In the case of commodities irradiated at a foreign or United States offshore facility. the USDA Plant Protection and Quarantine Officer at the port of entry will review the bill of lading, phytosanitary certificate, or other documentation accompanying the shipment, determine whether or not the shipment is precleared, and decide whether to inspect the commodity for actionable pests that might not have been mitigated by the treatment and might be vectored be the shipment. If non-target pests are encountered, the inspector shall make inquiry to irradiated, a perishable commodity cannot be re-irradiated. In the case of commodities arriving untreated (to be irradiated in the United States), the officer shall:

- review the documentation accompanying the shipment
- ensure compliance with biologically sound safeguards
- facilitate the planned movement of the shipment to an approved treatment facility

Permits

Importers must have, and present (to a USDA Plant Protection and Quarantine Officer at the port of entry) a valid permit before offering for entry of irradiated commodities or commodities intended for irradiation treatment in the USA. Permits may be obtained from:

United States Department of Agriculture (USDA),
Animal and Plant Health Inspection Service (APHIS),
Plant Protection and Quarantine (PPQ),
Permit Unit,
4700 River Road, Unit 133,
Riverdale, MD 20737-1236

For detailed information on permits, applicants may contact the APHIS web site at http://www.aphis.usda.gov/ppq/ss/permits.html. These permits give the conditions of entry requirements, procedures to be followed, commodities covered, accountability and other pertinent information. Permits should be secured at least 30 days in advance of arrival to ensure that ports can be contacted, provisions can be developed, and permits can be transmitted to permittees and ports in advance of arriving shipments. Permits will be provided only to a person or firm able to accept liability and exercise responsibility for the shipment while in the United States. Brokers, agents, and other second-party permittees must be able to demonstrate direct authority concerning the handling of transit shipments under their permit.

Standard Operating Procedures and the Compliance Agreement

General Information

Standard Operating Procedures (SOP) shall be developed and documented by each facility that address irradiation of commodities for mitigation of pests of plants. This document must be in place before the facility is offered for certification. It must include the "how to" for all facets of handling, safeguarding and treating the commodities. Critical control points are dose, dosimetry, and safeguards. Critical control points are points where errors will definitely reduce the long-term effectiveness of the treatment. (On the other hand, effort to ensure correct procedure at these points will result in substantially more effective treatments.) The SOP will be reviewed and scrutinized along with the facility and personnel qualifications in determining the acceptability for certification. Any required changes in this document shall be made before a Compliance Agreement can be issued. This document will be referenced as a part of a formal, written agreement between USDA and the facility. Such agreements shall be reviewed periodically, modified as needed, and treated as confidential.

Before operating as an approved irradiation plant pest treatment facility, a formal, written agreement shall be developed between the irradiation facility and USDA. This document is called a Compliance Agreement when applied to facilities in the United States. **PPQ Form 519 (Compliance Agreement)** may be used as a cover sheet for this document, with attachments as needed.

For foreign facilities, this document may be called a Cooperative Agreement or Work Plan. The signatories to a binational agreement with foreign facilities will include a representative of the irradiation facility, the national plant protection organization, and the USDA (i.e., the Administrator of APHIS, who may delegate this responsibility to

the Regional or Area Director of APHIS International Services who has responsibility for a particular country.) In the case of facilities applying regulatory treatments in Canada or Mexico, that country's delegate to the North American Plant Protection Organization may also be requested to sign. Regulatory officials shall have a Cooperative Agreement or Work Plan on hand, plus a copy of the treatment schedule for the particular pest and commodity being treated, in order to perform their duties as a regulatory official.

Importers also need to sign a separate Compliance Agreement with APHIS, to ensure that they move articles safely to the irradiation facility.

A Compliance Agreement (or equivalent) shall be valid until terminated by a request from the facility. USDA, however, shall suspend or terminate the agreement when any provision is not being met, or is being willfully violated. USDA also has statutory authority to impose civil penalties on facilities in the United States or at the port of entry for foreign facilities for significant noncompliance.

Components of the Compliance Agreement

Safeguarding

The Compliance Agreement, Cooperative Agreement or Work Plan shall describe the pertinent safeguards applicable to the particular facility. Safeguarding topics fall into three general categories:

1. Pretreatment
   - ❖ receiving
   - ❖ separation of treated from untreated commodities
   - ❖ packaging
   - ❖ marking/labeling
2. Processing
   - ❖ general sanitation
3. 3. Post-treatment
   - ❖ wrapping
   - ❖ loading of containers

The section for Safeguards (beginning on **page-3-8-10**) addresses the topic of safeguarding in greater depth.

Notifying the regulatory authority

USDA (or the host country's NPPO counterpart agency) shall be notified by the irradiation facility at least 24 hours before irradiating regulated domestic agricultural commodities, or 30 days for regulated foreign agricultural commodities, except if the treatments are ongoing or scheduled.

Treatments shall be subject to scrutiny by an approved inspector. During the initial phase, it is considered important for an inspector to be on site. Phase out of the inspector's presence can be accomplished over a period of time, after the level of confidence is built up that proper procedures are in place, and are working to achieve their goal. Thereafter, an inspector will usually not be physically present to monitor individual treatment procedures. Inspector visits may be announced or unannounced, and shall include an examination of treatment records, and spot-checks to verify that biological safeguards are being conducted.

Treatment verification

Dosimetry system - Use ASTM Standard E1261, Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing (or an equivalent international standard) as a guide for selection and calibration of an appropriate routine dosimetry system that matches the dosimeter requirements for the specific application criteria. Other individual ASTM standards (E 1204 and E 1431) provide detailed procedures for using specific dosimetry systems. (ASTM standards on dosimetry for radiation processing are published in the Annual Book of ASTM Standards, Volume 12.02, American Society for Testing and Materials, West Conshohocken, Pennsylvania.) Prior to use, the dosimetry system shall be calibrated in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. This calibration shall be repeated when appropriate to ensure that the minimum dose is given to the targeted pest(s). Calibration of dosimeters shall be traceable to a national standard.

Dose mapping- The irradiation facility shall perform sufficient validation studies (dose mappings) to fully characterize the distribution of dose in the irradiation container to determine the zones of minimum and maximum dose. Dose mapping activities shall be conducted with consideration of the density ranges of product categories to be processed. Product loading patterns and pathways used for irradiation processing shall also be addressed. The information from the dose mapping validation is used in the selection of dose monitoring locations for routine processing. Additional dose mapping is required when significant changes are made to the irradiator, to the load, fruit size, or packaging, that could affect the distribution and quantity of dose. Dose mapping shall comply with ASTM Standard E1204, Practice for the Application of Dosimetry in the Characterization of a Gamma Irradiation Facility for Food Processing, or ASTM Standard E1431, Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing.

Timer or cycle validation- Irradiation exposure times to assure delivery of the specified dose shall also be evaluated. In the case of radioisotope processing, this may involve validating timer settings

upon which product container movements are based, or in the case of electron or x-ray processing, validating conveyor speeds. Timers should be calibrated to NIST Time Signals.

Routine dosimetry- Routine dosimetry is part of a verification process for establishing that the irradiation process is in compliance. Dosimetry is only one component of a total quality assurance program for adherence to good manufacturing practices. An appropriate dosimetry system shall be selected, and dosimetry procedures shall be followed for irradiator characterization, process qualification, and routine processing, to ensure that all product has been treated with the minimum absorbed dose prescribed by USDA for mitigation of the particular target pest(s) presumed to infest/infect/contaminate a given commodity from a particular origin. If non-target pests (such as hitch hikers) are encountered, the inspector shall make inquiry to appropriate authorities as to treatment efficacy. The dosimetry system shall be periodically calibrated in accordance with ASTM Standard E1261, and is traceable to national or international standards. Proper dosimetric measurement procedures shall be employed, with appropriate statistical controls and documentation in accordance with ASTM Standard E1204 (for gamma facilities) or E1431 (for electron beam and x-ray [bremsstrahlung] facilities). Once the capability to process the items within prescribed absorbed-dose limits is established, it is necessary only to monitor and record the minimum and maximum absorbed dose during each production run, to verify compliance with the process specifications within a predetermined level of confidence. The facility SOP shall specify how frequently dosimeters will be used.

USDA shall require that each carton shall bear a radiation-sensitive indicator (RSI) as evidence of treatment. RSI's (such as labels, papers, or inks that undergo a color change when exposed to irradiation) are not quantitative, and therefore shall not be used as a substitute for proper dosimetry.

Notifying the exporter or receiver

The irradiation facility shall notify (by telephone, fax, or E-mail) the exporter, receiver, or other designated person, immediately upon completion of the irradiation processing of his consignment, to expedite delivery. When the irradiation treatment has been conducted in a foreign country, the irradiation facility shall also request the national plant protection organization to issue a phytosanitary certificate and apply official seals, if required.

Treatment documentation (record keeping)

Phytosanitary certificate, and certificate of treatment- For offshore arrivals at a United States port of entry, a phytosanitary certificate (with treatment information, if any, filled in), and the irradiation processor's certificate of treatment (if a treatment was done) must accompany the shipment.

Records kept at the plant- Key pieces of information (to include (either on the certificate of treatment or in back-up files) shall include:

- Name of the product and quantity
- Grower's lot (batch) identification (to be shown also on each carton)
- Prescribed treatment
- Evidence of compliance with the prescribed treatment
- Ionizing energy source
- Dosimetry system calibration records
- Dose mapping records
- Dosimetry data (minimum and maximum)
- Date of irradiation
- Records, invoices, and bills of lading for each treated lot (batch) must be kept for one year, and made available by the irradiation processor for inspection by designated regulatory officials.

Official seals- Irradiated shipments leaving a facility on the mainland United States do not need USDA seals if destined to domestic markets. If the shipment is destined to foreign markets, however, USDA shall apply seals and issue a Phytosanitary Certificate if required. Irradiated or untreated shipments leaving Hawaii for the mainland United States shall have official seals applied by USDA, if required. Irradiated or untreated shipments leaving a foreign country for the United States shall have seals applied by the national plant protection organization (NPPO) in the country where the facility is located, and/or by USDA, if required.

Important

Disclaimer: The United States Department of Agriculture and its inspectors do not assume liability for any loss or damage resulting from any treatment prescribed or super vised. Treatments are approved to assure biological security against designated pests. From the literature available, agricultural commodities authorized for treatment are believed to be tolerant to the prescribed dose. However, the facility operator and shipper are responsible for determination of tolerance. Additionally, the Nuclear Regulator y Commission is responsible for ensuring that irradiation facilities are constructed and operated in a safe manner. Further, the Food and Drug Administration is responsible for ensuring that irradiated foods are safe and wholesome for human consumption [21 CFR par t 179].

SAFEGUARDING IRRADIATION TREATMENT FACILITIES

General Information

Safeguards may be aimed either at preventing the treated commodity from becoming reinfested, or preventing the surrounding environment from becoming infested by pests escaping from the untreated commodity. Pests of concern typically include Tephritid fruit flies, wood-boring insects, surface feeders such as mites, and miscellaneous hitchhikers such as snails.In some cases, the pests may be noxious weed seeds or plant disease organisms. The Compliance Agreement will specify the phytosanitary safeguards to be observed at the facility. If the pest risk cannot be mitigated, then shipment of product to the facility shall be disallowed.

The location of the irradiation facility, and the sensitivity of the surrounding environment are important considerations in determining which safeguards apply in a given case. At foreign facilities, the national plant protection organization of the particular country should also become involved. Other considerations include whether the commodity is treated in bulk or in the final package, and whether the target pests, due to their mobility, present an unusual risk.

USDA has a great deal of latitude in prescribing safeguards for individual facilities. This is particularly necessary, considering the various circumstances under which the treatment operation will be conducted. Details of a particular safeguarding regimen shall be established in cooperation with the facility manager, and tailored to meet existing circumstances. If the commodities/pest complexes/product origins change at a particular facility, the safeguarding program shall be adjusted accordingly, with appropriate amendments or revisions made to the Compliance Agreement. The purpose of all mitigation and safeguarding activities is to prevent pests from moving from infested ecosystems to non infested ecosystems.

Safeguards

The following seven critical safeguarding topics, as addressed in the Compliance Agreement[1], are discussed in this section:

- Receiving
- Separation of treated from untreated commodities
- Packaging
- Marking/labeling

1 Refer back to ""Components of the Compliance Agreement" on **page-3-8-6**" for a detailed discussion of the requirements for notification, treatment verification, and documentation.

- General sanitation
- Wrapping
- Loading of containers

The USDA may require any of these safeguards under the following three different scenarios as described on **page-3-8-14**):

- Scenario 1: The irradiation facility is located within an infested area.
- Scenario 2: The irradiation facility is not located within an infested area, but the surrounding environment is susceptible to the target pests.
- Scenario 3: The irradiation facility is not located within an infested area, and the surrounding environment is not susceptible to the target pests.

Receiving

A record of origin (growing and shipping points) must accompany all arrivals at the facility.

For Scenarios 1 and 2, vans and sea containers used for delivery should form a pest-secure connection with the receiving area of the building, if pests are mobile. However, this would not be necessary if the commodity arrives in pest-proof cartons, or is wrapped in polyethylene (or equivalent) sheeting or insect netting. For Scenario 2, the irradiation facility shall not be allowed to receive the product that arrives non containerized (e.g., in an automobile or pickup truck). If a pest-secure connection is not possible, then the receiving door shall be opened for the minimum time possible, while the unloading is being expedited. (These precautions are not necessary in Scenario 3.)

When empty, the sea containers, truck vans, and air cargo containers in which the commodity arrived shall be swept clean, and the sweepings bagged and irradiated to at least the minimum dose designated for the product, or destroyed in a manner approved by USDA. If pests are at large in the emptied container, the container shall be treated immediately with a suitable insecticide, followed by visual inspection. (Use an aerosol insecticide for mobile pests, or a residual spray for others, following instructions on the label.)

Irradiation processing of agricultural commodities shall be expedited, to retard the development and possible emergence of pests from the commodity. USDA recommends that the consignment be kept in temporary cool storage if it is not possible to irradiate it within 24 hours of arrival.

Separation of treated from untreated commodities

The facility shall have a reliable system for separating treated from untreated products, to safeguard against commingling, cross-infestation, mistaken identity, and release without treatment. In Scenarios 1 and 2, the physical barrier shall also be a pest-proof (biological) barrier (i.e., a solid wall or a screen with a mesh size fine enough to exclude flying insects), unless the commodity arrives in pest-proof cartons, or if the target pests are immobile. In Scenario 3, a 6-ft barrier, such as a chain link fence, is adequate for all pests, and the type of carton is of minor importance

Packaging

The commodity shall arrive at the facility in pest-proof packaging if the pests are mobile, except if a pest-proof barrier (between pretreatment and post-treatment storage areas) is in place at the facility. This provision would apply only in Scenarios 1 and 2. If pests are not mobile, or if the surrounding area is not susceptible to infestation by the target pests in Scenario 3, then the type of packaging becomes less important. Seals or other devices may be used to visually indicate if packages have been opened. For pests that are not mobile, simple containment is the key, and the integrity of the container load is the main concern. Pest-proof packages, if required, may be constructed of any material that prevents the entry or escape of the pest, prevents egg-laying into the carton, and the dispersal of pupae. If openings in the carton are needed in order to maintain freshness of the commodity, they shall be double screened.

Important

If there are any questions concerning the adequacy or biological security of a particular package or configuration, shippers may send a sample for evaluation to:

Oxford Plant Protection Laboratory
USDA, APHIS, PPQ
901 Hillsboro Street
Oxford, NC 27565
Tel: 919-693-5151
Fax: 919-693-3870

Marking / Labeling

In order to enable trace-back of shipments, unit loads shall be labeled or coded with identifiable treatment lot or batch numbers, packing and treatment facility identification and location, and the dates of packing and treatment. In addition, each carton (or smallest containment unit) shall bear a stamp identifying the lot or batch number and treatment facility. The markings on individual packages may be encrypted (e.g., bar coding). If the pallet load is broken down into smaller units before or during the process of entering the United States, the individual cartons must be labeled with the same information as the original pallet load.

Cartons treated under USDA super vision in Hawaii shall be stamped TREATED--USDA APHIS. This may not be preprinted on the carton at the time of manufacture.

In the case of food commodities, the United States Food and Drug Administration (FDA) also requires the international irradiation logo (radura) to appear on each carton, along with the statement Treated by irradiation or Treated with radiation. (This may be preprinted on the carton.)

General Sanitation

A high level of sanitation shall be maintained around the facility, as well as within the pre- and post-treatment storage areas, and the equipment used for transporting the product through the irradiator. Windows, if they are going to be opened, must be equipped with screens. Facilities are advised to install black light traps for flying insects, and to contract with a pest control firm. Critical concerns of USDA include pest monitoring and minimizing the attractiveness of treatment facilities for pests. Disposal procedures shall be in place for rotted produce, produce with damaged packing, and produce that has been improperly irradiated. These materials shall be irradiated, at a dose sufficient to mitigate the potential pest risk, prior to disposal by incineration or burial in a sanitary landfill, if required by USDA. The area of the floor where the commodity is loaded onto the conveyor shall be swept clean at the end of the day, and the debris shall be bagged and irradiated to at least the minimum dose designated for the product.

Wrapping

Maintain the integrity of the pallet load or other configuration of packages representing a treatment unit by wrapping it before it leaves the irradiation facility. In Scenarios 2 and 3, (where the irradiation facility is not located within an infested area), a suitable method of wrapping would be to use strapping, so that each carton on an outside row of the pallet load is constrained by a metal or plastic strap. In Scenario 1, (where the irradiation facility is located in an infested area), the treatment unit shall be wrapped in polyethylene (or equivalent) sheet wrap or fine net wrapping. USDA, however, may waive the requirement for post-treatment wrapping if the cartons are pest-proof, and the pallet load is to be broken down into smaller shipping units, such as LD-3 air cargo containers or individual cartons.

Loading of containers

Empty containers or vans shall be carefully inspected, and decontaminated (if necessary), prior to loading with treated product. Empty containers shall be swept clean, and the sweepings bagged and put through the irradiator. If pests are at large in the empty container, the container shall be treated immediately with a suitable insecticide, followed by visual inspection. (Use an aerosol insecticide for mobile pests, or a residual spray for others, following instructions on the label.) In Scenario 1 (where the facility is located in an infested area), if the pests are mobile, special care should be taken to prevent the reentry of untreated pests into the treated product. The conveyance

shall be pest-proof. In addition, the driver shall make every effort to form a pest-secure connection between the conveyance and the building. If this is not possible, then the door to the loading dock shall be opened for the minimum time possible, while loading is being expedited. This precaution is not needed in Scenarios 2 and 3 (where the irradiation facility is not located in an infested area).

Three Scenarios

Scenario 1: The irradiation facility is located within an infested area.

The purpose of the safeguards, in this instance, is to protect the treated commodity from becoming re-infested. The following safeguarding topics would all seem to apply in scenario 1:

- receiving
- separation of treated from untreated commodities
- packaging
- marking/labeling
- general sanitation
- wrapping
- loading of containers

For **"separation of treated from untreated commodities"**, a screen or solid wall would be an important feature only if pests are mobile. Pest-proof **"packaging"** would also be an option in this case. Also, if the pests of concern are mobile, an appropriate **"wrapping"** option would be polyethylene (or equivalent) sheet wrap or net wrap. When you are **"loading containers"** loading of containers, a pest-secure connection to the building would be appropriate only if the pests are mobile and could fly in from outside the building.

Scenario 2: The irradiation facility is not located within an infested area, but the surrounding environment is susceptible to the target pests.

The purpose of safeguards, in this instance, is to protect the surrounding environment from escaping pests that have not been treated. However, owing to the high level of pest risk posed by this scenario, USDA and/or the particular state involved may not allow importation of untreated (potentially infested) commodities to an irradiation facility located within a sensitive, receptive environment in

the United States, without stringent safeguards and quality assurance activities. If this scenario were allowed, then the following safeguarding topics would be critically enforced:

- marking/labeling
- general sanitation
- wrapping

If the pests are mobile, then the following safeguarding topics would certainly apply, as well:

- receiving
- separation of treated from untreated commodities
- packaging

"Loading of containers" would not apply, since any surviving pests that escape into the environment would be sterile, and pose no risk.

Scenario 3. The irradiation facility is not located within an infested area, and the surrounding environment is not susceptible to the target pests.

Applicable safeguarding guarding, in this instance, include:

- separation of treated from untreated commodities
- general sanitation
- wrapping

For "separation of treated from untreated commodities", a 6-ft high barrier would suffice, except for mobile pests. For "wrapping", the strapping option may provide adequate quarantine security, though polyethylene (or equivalent) sheet wrap or netting could also be suitable.